



L'Hôpital de Montréal pour enfants  
The Montreal Children's Hospital  
Centre universitaire de santé McGill  
McGill University Health Centre

## PEDIATRIC RESEARCH INFORMATION AND CONSENT FORM

**Title :** Egg Desensitization and Induction of Tolerance in Children

**Name of Participant :**

**Persons responsible :**

- Montreal Children's Hospital- McGill University Health Center: Dr Bruce Mazer

Dr Moshe Ben-Shoshan

Dr Christine McCusker

**Funding Source:** AllerGen NCE, Inc

### WHY ARE YOU BEING INVITED TO TAKE PART IN THIS STUDY?

The Allergy department participates in research studies to try to improve treatments for children with egg allergy. Today, we are inviting you to take part in a research study. Please read this information to help you decide if you want to participate in this research project. It is important that you understand this information. We encourage you to ask questions. Please take all the time you need to make your decision.

We encourage parents to include their child in the discussion and decision making to the extent that the child is able to understand.

In this research information and consent form, "you" means you or your child.

### WHY IS THIS STUDY BEING DONE?

The purpose of this study is to assess a treatment protocol that may help children with egg allergy tolerate egg. This process is called Oral Immunotherapy and involves 2 treatment periods: 1) gradual supervised exposure to egg in our research unit; 2) Supervised exposure to egg at home.

### BACKGROUND

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You have egg allergy. Typically with patients with food allergies, treatment consists of avoiding the allergenic food and managing reactions when they occur, but not of removing the actual allergy. Recent studies have shown that people with food allergies can be made 'tolerant' (meaning they won't react) to foods to which they had previously reacted by very slowly introducing the allergenic food. We want to see if by using our protocol, we can make patients who are allergic to egg tolerant to egg.

### **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

About 45 patients recruited from the McGill University Health Center.

### **WHAT WILL HAPPEN ON THIS RESEARCH STUDY?**

The desensitization process consists of three stages: a blinded, oral food challenge, an escalation/home dosing phase and a maintenance phase. After the first stage, the blinded oral food challenge, you will be randomly assigned (like flipping a coin) to receive either oral immunotherapy (treatment group) or follow-up only (control group) during one year. During the study, participants in both groups will be invited for follow-up in which their allergy status as well as tests assessing potential tolerance to egg will be taken. We will also ask you to keep a diary documenting your symptoms during the study period. These will take no more than 20 minutes per visit to complete. In addition, a sample of approximately 20ml of blood (about four teaspoons) will be taken from a vein in your arm initially and during the follow-up period (every 3 months for 1 year). We will also collect 5ml of saliva on the same days as the blood draws. You will also have skin prick testing (SPT) to egg done. All these tests are being done to assess the changes that are taking place in your body during the desensitization process. We hope that using the results from these tests will help us predict which children can be expected to tolerate the desensitization process and which children will tolerate it less well. Children in the follow-up only group will be invited to participate in oral immunotherapy after the follow-up year. We will also review your medical records at the Montreal Children's Hospital. This will enable us to determine the tests performed in order to diagnose your egg allergy.

You will be contacted every 1-3 months by our research team (either by email or phone according to your preference) during the following year and be asked about accidental exposure and potential allergic reactions.

#### Oral Immunotherapy (OIT)

Oral Immunotherapy for egg is a way to allow people with egg allergy to eat the food they're allergic to without having a reaction and incorporate it into their diet. There are four stages to Oral Immunotherapy (OIT).

#### Blinded Oral Egg Challenge

The first stage of OIT is a blinded oral egg challenge. This is done to be absolutely sure that you are allergic to egg. During the challenge, you will be given bigger and bigger amounts of powdered egg, alternating with something that you are not allergic to, like wheat flour. The challenge is blinded, meaning that you will not know if you receive the egg or the wheat flour first. This visit will last approximately seven hours.

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The way the challenges work is as follows:

1. You will come to the Centre for Innovative Medicine in the morning. You will have an intravenous line put in your arm. This is so that if you have an allergic reaction, medication to treat the reaction can be given as quickly as possible.
2. Once you have the intravenous put in, you will be given a small dose (0.2 ml) of either egg powder or placebo (a product to which you are not allergic). You will not be told which one you are getting.
3. Every 30 minutes, you will be given a larger amount of egg powder or placebo, up to 200 mg.
4. If the study doctor feels that you are having an allergic reaction, the challenge will stop, you will be given medication to treat the allergic reaction and will not take any more of the product.
5. To ensure that you are safe and don't have a late reaction, you will stay at the hospital under the observation of the study staff for at least two hours after the end of the challenge. If you react to egg, you will be considered to have had a positive challenge, and thus be eligible for the study.

#### Escalation/Home Dosing Phase

This phase is where you start being exposed to egg, with the eventual goal of making you tolerant to egg (meaning that you will not have an allergic reaction to it if you eat some)

1. During this phase, you will start eating powdered egg at home. The dose at which you will start will be determined during the oral food challenge. Your first home dose will be the last dose you were able to eat without reacting during the challenge. For example, if during the challenge you reacted to 50 mg of egg powder, you will start home dosing at 25 mg, which is the last dose before 50 mg. This will continue for two weeks.
2. After two weeks, you will come to the hospital and, under the supervision of the study staff, will increase your dose of egg powder
3. For the next two weeks, you will take this daily dose at home.

At the end of two weeks, you will come back to the hospital and again under the supervision of the study staff, eat the next dose of egg powder. This dose will be consumed at home for the next two weeks. This process of coming to the hospital and eating a slightly larger amount of egg and eating the same amount at home will continue until you reach 300 mg of egg powder, then you will start the maintenance phase.

#### Maintenance Phase

This phase will last twelve months.

1. For the first three months of this phase you will eat 300 mg of egg a day.
2. After three months, you will come to the hospital for another blinded oral egg challenge. This will be different from the challenge you did at the beginning of the study in that it will be a two-day challenge: on one day you will receive either egg powder or placebo, and on the second day will receive whichever of the two you did not receive on the first day. You will be blinded during these challenges, meaning that you will not know if you received placebo or egg powder. The doses will go to higher levels than at the initial challenge

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3. You will come to the hospital on three more occasions during this period, at 6, 9 and 12 months post Oral Immunotherapy. During these visits you will have skin, blood and saliva tests done. At the last, 12 month visit, you will do one more blinded, oral food challenge.

#### **FOR HOW LONG WILL YOU PARTICIPATE IN THIS STUDY?**

Participation in the study will last about 18 months. Some people take longer to achieve desensitization, so the amount of time you spend in the study might be longer than 18 months. In order to respect the study timeline, participants who are not able to tolerate the 300 mg maintenance dose by 18 months following the initiation of the desensitization process will have to leave the study.

#### **WHAT ARE THE RISKS?**

If you are assigned to the oral immunotherapy group, you might have allergic reactions during this treatment. These reactions can include nausea, abdominal pain, vomiting, or inflammatory disease of the esophagus (known as eosinophilic esophagitis). You may also experience skin symptoms such as hives or itchiness. Rarely, more severe reactions such as breathing problems may occur. Your reactions will be monitored and treated promptly during the desensitization process in our allergy unit by our team and if deemed necessary by our medical team the therapy will be stopped. You will also receive detailed instructions for treating reactions should they occur during the home phase of therapy. You will be given the phone numbers of members of the study team, whom you can call if you need advice about any aspect of the study. All subjects on treatment will be given an adrenalin auto-injector (Twinject or EpiPen) as a precaution.

The risks of having blood drawn include pain where the needle is put in, minor bleeding, bruising, and fainting. A topical anesthetic (freezing) cream can be used to decrease the pain. All of these rarely occur and do not cause any long lasting problems.

Should you suffer an injury of any kind following administration of the study drug, or following any other procedure related to the research study, you will receive the appropriate care and services required by your state of health.

#### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

Your participation in this research will provide potential benefit if you are assigned to the oral immunotherapy treatment group and if the therapy is successful. If you are not assigned to receive desensitization there will be no direct benefit. However, the information collected from this study may help us better understand and design future therapies. All participants randomized to the control group will be offered the opportunity to undergo oral desensitization to egg once their year in the control group has expired.

#### **WHAT OTHER OPTIONS ARE THERE?**

Instead of participating in this research project, you could choose the standard treatment, of avoiding egg and treating the reactions if you are exposed to eggs. Please discuss the different options you have with your doctor.

#### **WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

Other than transportation costs, there are no costs associated with participating in the study.

#### **IS ANY COMPENSATION BEING OFFERED?**

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No monetary compensation is offered.

## **HOW IS PRIVACY ENSURED?**

During your participation in this study, the study doctor and their team will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of the study.

The study file may include information from your medical chart [Optional: including your identity,] concerning your past and present state of health, your lifestyle, as well as the results of the tests, exams, and procedures that you will undergo during this research project

The blood and saliva samples will be analysed at the McGill University Health Center Research Institute and conserved for 5 years for the exclusive objectives of this study and then destroyed.

All information obtained during the study will be kept confidential as required or permitted by law. Your identity will be protected by replacing your name with a research number. Only the research team at your own hospital will have access to the code linking your name to this number.

To ensure your safety, a copy of this information and consent form will be placed in your medical chart. As a result, any person whom you give access to your medical chart will have access to this information.

The study data will be stored for 25 years by the study doctor

The data may be published or shared during scientific meetings, however it will not be possible to identify you.

For monitoring, control, safety, and security, your study file as well as your medical charts may be examined by a person mandated by Canadian or international regulatory authorities, such as Health Canada, as well as by representatives of the institution, or the Research Ethics Board. All these individuals and organizations adhere to policies on confidentiality.

You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

However, in order to protect the scientific integrity of the research project, accessing certain information before the project is ended may require that you be withdrawn from the study.

## **IS YOUR PARTICIPATION VOLUNTARY AND CAN YOU WITHDRAW?**

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study doctor or a member of the research team.

Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the study doctor or clinical team.

The study doctor, or the Research Ethics Board may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

However, before you withdraw from the study we suggest, that you return to the clinic for a final evaluation, for safety reasons.

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If you withdraw or are withdrawn from the study, the information collected during the study will nonetheless be stored, analyzed or used to protect the scientific integrity of the research project.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

#### **WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have any questions about this research project or if you suffer any problems you believe are related to your participation in this research, you can call the researcher responsible for the project in your hospital:

Montreal Children's Hospital: Dr. Bruce Mazer at (514) 412-4470

In case of emergency, please go directly to the closest emergency room.

If you would like information about your rights related to your participation in the research, you may contact the hospital Ombudsman (Patient Representative):

- Montreal Children's Hospital: 514-412-4400, poste 22223

#### **RESEARCH ETHICS COMMITTEE**

The research ethics committee of McGill University Health Center approved this project and will monitor the project.

## CONSENT AND ASSENT FORM

### Title of this research project: **Egg Desensitization and Induction of Tolerance in Children**

I have been explained what will happen on this study. I read the information and consent form of 8 pages including the annexes and was given a copy to keep. I was able to ask my questions and they were answered to my satisfaction. After thinking about it, I agree to, or I agree that my child will, participate in this research project.

I authorize the research team to consult my medical records or the medical records of my child to collect the information relevant to this project.

By agreeing to participate in this research project, you are not waiving any of your legal rights nor discharging the study doctor, the sponsor or the institution, of their civil and professional responsibilities.

Name of participant (Print)	Assent of minor, capable of understanding the nature of the research (signature) or Verbal assent of minor obtained by:	Date
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Name of parent(s) or legal guardian (Print)	Signature	Date
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Name of participant (18 years +) (Print)	Signature	Date
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I have explained to the participant and/or his parent/legal guardian all the relevant aspects of this study. I answered any questions they asked. I explained that participation in a research project is free and voluntary and that they are free to stop participating at any time they choose.

Name of Person obtaining consent (Print)	(signature)	Date
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**Addendum to consent form**  
**Participant who has now become an adult (18)**

**Title of research project :** \_\_\_\_\_

Today, I reviewed the information and consent form that my parents signed on my behalf when I enrolled in this research project and a copy of that signed consent was given to me.

I agree to continue my participation in this research project.

I understand that my participation is free and voluntary and that I can stop participating in this research project at any time I choose.

I authorize the research team to consult my medical records to collect the information relevant to this project.

If I withdraw, any remaining samples or data that has not already been analyzed will be destroyed.

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Name of participant	Signature	Date
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Name of person obtaining consent	Signature	Date
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